IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF ARKANSAS
FORT SMITH DIVISION

REBECCA SHARP **PLAINTIFF**

V. **CASE NO. 2:20-CV-2028**

ETHICON, INC. and
JOHNSON & JOHNSON **DEFENDANTS**

MEMORANDUM OPINION AND ORDER

Currently before the Court are a Motion for Partial Summary Judgment (Doc. 20) and Brief in Support (Doc. 21) filed by Defendants Ethicon, Inc. and Johnson & Johnson. Plaintiff Rebecca Sharp filed a Response in Opposition (Docs. 22 & 23) and Defendants filed a joint Reply (Doc. 25), making the Motion ripe for decision.

This case was recently transferred to this Court from the District Court for the Southern District of West Virginia, where the Honorable Joseph R. Goodwin was presiding over seven separate multi-district litigations ("MDL") concerning products sold by the Defendants. This case was related to one of the seven MDLs. *See* Transfer Order, Doc. 30. The Court has now considered the briefing on Defendants' Motion for Partial Summary Judgment and finds that the Motion should be **GRANTED** for the reasons described herein.

I. BACKGROUND

The short-form Complaint (Doc. 1)—which is the operative complaint filed in this case—lists 18 separate causes of action but very few facts. Defendants move for summary judgment on Counts II, III, IV, VII, X–XIII, and XV. Plaintiff Sharp agrees that all of those claims lack merit except for Count III. Therefore, Counts II, IV, VII, X–XIII, and XV will be dismissed *with prejudice* on summary judgment. Ms. Sharp also states in

her Response to the Motion that she will "not be proceeding" with Counts VI, VIII, IX, and XIV, so those claims will be dismissed *without prejudice* pursuant to Federal Rule of Civil Procedure 41(b). The only remaining claim to be decided on summary judgment is Count III, which is a strict liability claim for failure to warn.

Ms. Sharp is a 49-year-old woman who was previously diagnosed with symptomatic stress urinary incontinence, a condition that results in involuntary leakage of urine.[1] To treat this condition, her doctor, Dr. David Crownover, recommended that she undergo surgery and be implanted with a medical device called a TVT-Obturator ("TVT-O"). Dr. Crownover performed the surgery implanting the TVT-O at a hospital in Siloam Springs, Arkansas, on February 15, 2010. The Court understands that the device is a polypropylene mesh product commonly described as "tension-free vaginal tape" that is fixed in the pelvis through insertion and placement in the obturator membranes. (Doc. 22-2, pp. 5, 7).

Following the surgery, Ms. Sharp claims that she developed "pain and dyspareunia . . . that has been ongoing to the present day," which she attributes to the TVT-O device. (Doc. 23, p. 2).[2] In Count III, Ms. Sharp asserts that the Defendants should be held strictly liable for their failure to provide adequate warnings of the risks associated with the device.

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[1] There are essentially no background facts in the short-form Complaint, nor are there any facts in Defendants' Brief in Support of the Motion for Partial Summary Judgment. Ms. Sharp offers a few facts in her Brief in Opposition, and Defendants do not specifically contest the veracity of those facts in their Reply. Therefore, for purposes of summary judgment, the Court will assume that the facts in Ms. Sharp's Brief are true.

[2] Dyspareunia is the medical term for painful intercourse. https://www.mayoclinic.org/diseases-conditions/painful-intercourse/symptoms-causes/syc-20375967 (accessed on March 17, 2020)

She argues that a genuine, material dispute exists as to whether Dr. Crownover was adequately warned of the risks associated with the TVT-O device. Ms. Sharp contends that nothing in Defendants' patient brochures related to the device indicated that it could cause dyspareunia and frequent, severe, or permanent pelvic pain. She maintains that under the so-called "learned intermediary rule," which Arkansas law recognizes, Defendants were obligated to provide sufficient warnings about the device to Dr. Crownover. She believes that if her doctor had been given complete information about the risks of the device and passed those risks on to her, she would have decided not to have the surgery.

Defendants point out that Dr. Crownover testified in his deposition that he did not rely on the manufacturer's product warnings in making the recommendation to Ms. Sharp that she have the surgery and be implanted with the device. Defendants argue that without evidence of such reliance by Dr. Crownover, Ms. Sharp will be unable to establish at trial the necessary causal connection between the (allegedly inadequate) warnings and her post-surgery injuries. Further, Defendants maintain that Dr. Crownover testified that even if different product warnings had been offered to him, he would not have changed his mind about recommending the implantation of the device, as he believed at the time and believes today that the TVT-O device is safe and effective.

Below, the Court will begin its discussion by determining which state's substantive law applies to the dispute. Ms. Sharp asserts that Arkansas law applies, while Defendants argue in favor of Oklahoma law. Then, the Court will take up whether Ms. Sharp's failure-to-warn claim should survive summary judgment.

II. LEGAL STANDARD

The standard for summary judgment is well established. Under Federal Rule of Civil Procedure 56(a), "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." The Court must review the facts in the light most favorable to the opposing party and give that party the benefit of any inferences that can be drawn from those facts. *Canada v. Union Elec. Co.*, 135 F.3d 1211, 1212–13 (8th Cir. 1997). The moving party bears the burden of proving the absence of a genuine dispute of material fact and that it is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986); *Nat'l. Bank of Commerce of El Dorado, Ark. v. Dow Chem. Co.*, 165 F.3d 602 (8th Cir. 1999).

Once the moving party has met its burden, the non-moving party must "come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita*, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(c)). However, "the mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient" to survive summary judgment. *Anderson v. Durham D&M, L.L.C.*, 606 F.3d 513, 518 (8th Cir. 2010) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986)). Rather, in order for there to be a genuine issue of material fact that would preclude summary judgment, the non-moving party must produce evidence "such that a reasonable jury could return a verdict for the nonmoving party." *Allison v. Flexway Trucking, Inc.*, 28 F.3d 64, 66 (8th Cir. 1994) (quoting *Anderson*, 477 U.S. at 248).

III. DISCUSSION

A. Choice of Law

A federal court sitting in diversity applies the choice of law principles of the state in which it sits. *See Platte Valley Bank v. Tetra Fin. Grp., LLC*, 682 F.3d 1078, 1082 (8th Cir. 2012); *Prudential Ins. Co. of Am. v. Kamrath*, 475 F.3d 920, 924 (8th Cir. 2007). In tort cases, Arkansas courts look to the doctrine of *lex loci delicti*—or the law of the place where the wrong occurred—as well as to Professor Robert A. Leflar's five choice-influencing considerations. *See Gomez v. ITT Educ. Servs., Inc.*, 348 Ark. 69, 77 (2002) (describing the Leflar factors as "softening" the "rigid formulaic application" of the *lex loci deliciti* doctrine). "These five factors are as follows: 1) predictability of results; 2) maintenance of interstate and international order; 3) simplification of the judicial task; 4) advancement of the forum's governmental interests; and 5) application of the better rule of law." *Id.* at 76–77.

Application of the *lex loci delicti* doctrine plainly counsels in favor of using Arkansas law. The implantation of the TVT-O device—which allegedly led to all of Ms. Sharp's injuries—took place in Arkansas. Defendants argue that even though the alleged wrong took place in Arkansas, this Court should apply Oklahoma law because Ms. Sharp "is a long-time resident of Oklahoma and works in Oklahoma" and "has sought treatment for her injuries in Oklahoma." (Doc. 21, p. 3). Defendants' arguments are unpersuasive to the Court and do not undermine the fact that the *lex loci* of this case is Arkansas.

Moving on to the Leflar factors, the Court believes that applying Arkansas substantive law to the dispute would best maintain the predictability of results. This is because in a case involving the surgical implantation of an allegedly defective medical

device, it is expected—due to the application of the *lex loci delicti* doctrine—that the law of the state where the surgery took place would govern the dispute. The Court also believes that the interest in the maintenance of interstate order is well served by applying Arkansas law because Arkansas has significant contacts with the Plaintiff, her doctor, and the hospital where the allegedly defective medical device was implanted. Finally, Defendants concede that "Arkansas has an interest in protecting those injured by negligent conduct within its borders." *Id.* at p. 4 (quoting *Lane v. Celadon Trucking, Inc.*, 543 F.3d 1005, 1011 (8th Cir. 2008)). For all these reasons, the Court will apply Arkansas law to Count III.[3]

B. Count III: Failure-to-Warn

Under Arkansas law, "the manufacturer of a product has a duty to warn the user of dangers inherent in that product under the theories of strict liability, negligence and breach of warranty, and the comment k defense."[4] *Hill v. Searle Labs.*, 884 F.2d 1064, 1070 (8th Cir. 1989). However, Arkansas law also acknowledges that one of the exceptions to a manufacturer's duty to warn is "the learned intermediary rule, which assumes that it is reasonable for a manufacturer to rely on the prescribing physician to forward to the patient, who is the ultimate user of the drug products, any warnings regarding their possible side effects." *Id.* This rule recognizes that "medical ethics and practice dictate that the doctor must be an intervening and independent party between

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[3] The Court does not find that the third and fifth Leflar factors are materially relevant to the choice of law analysis in this case.

[4] The "comment k defense" refers to comment k to Section 402A of the Restatement (Second) of Torts, which deals with "unavoidably unsafe products" and defines them as those that carry "a medically recognizable risk" but may nonetheless be marketed and sold with proper warnings of the risk.

patient and drug manufacturer," that "the information regarding risks is often too technical for a patient to make a reasonable choice," and that "it is virtually impossible in many cases for a manufacturer to directly warn each patient." *Id.* "Thus, a warning to the [physician] is deemed a warning to the patient; the manufacturer need not communicate directly with all ultimate users of [medical devices]." *Kirsch v. Picker Int'l, Inc.*, 753 F.2d 670, 671 (8th Cir. 1985).

Here, the parties agree that Defendants reasonably relied on Dr. Crownover to review the product warnings and risks associated with the TVT-O device and convey those warnings to Ms. Sharp. Consequently, according to the learned intermediary rule, Defendants were legally obligated to provide "meaningful and complete" warnings *to Dr. Crownover*, but not to Ms. Sharp directly. *Hill*, 884 F.2d at 1071. Furthermore, when a physician like Dr. Crownover assumes the duty to pass on product warnings to his patient, the plaintiff's burden of proving a failure-to-warn claim is altered. Now she must prove:

> (1) that the [manufacturer] failed to warn the physician of a risk associated with the use of the product, not otherwise known to the physician, and (2) *that the failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury.* Because the defective aspect of the product must cause the injury, the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e. that but for the inadequate warning, the treating physician would not have used or prescribed the product.

Brinkley v. Pfizer, Inc., 772 F.3d 1133, 1138 (8th Cir. 2014) (emphasis in original) (quoting *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1098–99 (5th Cir. 1991)). This means that if a plaintiff's doctor is given "actual knowledge of the dangers" but claims that he "would have taken the same course had warnings been communicated, the doctor's independent knowledge breaks the causal link, and the plaintiff cannot recover" under a failure-to-warn theory. *Ideus v. Teva Pharm.*, 361 F. Supp. 3d 938, 946 (D. Neb. 2019) (collecting cases).

Defendants suggest that even if the Court were to assume for the sake of argument that the TVT-O product warnings given to Dr. Crownover were somehow inadequate, Ms. Sharp still would not be able to prove at trial that her alleged injuries were proximately caused by these defective warnings. Defendants have attached relevant portions of Dr. Crownover's deposition testimony to their Motion, which demonstrate that he was aware—both at the time of his deposition and at the time of Ms. Sharp's surgery in 2010—that there were certain risks associated with the TVT-O device, including wound complications, fistula formation, inflammation, neuromuscular problems, the need for one or more surgeries to treat an adverse event, the possible recurrence of the underlying medical condition or the failure of the device, erosion/exposure/extrusion of the mesh, and contraction of the tissues. (Doc. 20-4, p. 3). He agreed that all of these complications could be "mild, moderate, or severe." *Id.*

Dr. Crownover further testified that he did not rely on the "Instructions for Use" ("IFU") in making the decision to prescribe the device for Ms. Sharp. *Id.* at p. 4. Instead, he stated that he drew his knowledge of the risks of the product from his own training and experience and from his review of the medical literature *Id.* at p. 3. In response to questions relating to the failure-to-warn claim, Dr. Crownover made a number of material statements that, in the Court's view, foreclose the possibility of Ms. Sharp establishing a causal connection at trial between the content of the product warnings and her injuries.[5] The relevant portion of Dr. Crownover's deposition is as follows:

> Q Doctor, I'm going to show you what I've marked as the TVT-O that were in effect at the time of Ms. Sharp's TVT-O implantation.

[5] Importantly, Ms. Sharp did not attempt to mitigate, qualify, or otherwise explain any of Dr. Crownover's testimony excerpted here.

Q When you first learned about the TVT-O, did—would you have read the IFUs at that time or not?

A I'm not sure. Again, because of the training in residency, I'm not sure that I would have read this.

Q Okay. Do you think you've ever read the IFUs for the TVT-O?

A Likely, yes.

Q Okay. Do you have any recollection of when you might first have done that?

A I don't know exactly, but it does look familiar to me. But I don't know exactly when I would have read it.

Q Do you think you would have reviewed it more than once or—or not?

A Probably would have reviewed it more than once, yes.

. . .

Q Okay. And is the IFU something that you relied on in making the decision to prescribe the TVT-O for Ms. Sharp or no?

A No.

. . .

Q If Ethicon had included in the TVT IFUs the words found under the mesh column in Exhibit No. 8, is it correct to say that those additional words being added to the IFUs would not have changed your decision to prescribe the TVT-O for Ms. Sharp?

A They would not have influenced whether I offered that or not.

. . .

Q Putting yourself back at the time that you implanted Ms. Sharp's TVT-O in 2010, but with the knowledge that you have today, do you agree that the TVT-O was a safe and effective treatment for her stress urinary incontinence?

A Yes.

. . .

Q Putting yourself back at the time that you implanted Ms. Sharp's TVT-O, but based on the information and knowledge you have today, do you agree that the potential benefits of using the TVT-O to prevent or to treat SUI [Stress Urinary Incontinence] outweigh the potential risks?

A Yes.

. . .

Q *Okay. Knowing everything you know today, do you still stand by your decision to prescribe the TVT-O for Ms. Sharp?*

A *Yes.*

Q *Is there anything that Plaintiff's counsel has told you during the course of this deposition that would have changed your decision to prescribe the 7 TVT-O to her?*

A *No.*

Id. at pp. 3–6 (emphasis added).

In view of this unrefuted testimony by Dr. Crownover, who was the treating physician and surgeon who prescribed and implanted the TVT-O for Ms. Sharp, Count III must be dismissed. There is no genuine, material dispute that deficient product warnings related to the TVT-O device were the proximate cause of Ms. Sharp's injuries, since Dr. Crownover testified—without qualification—that different warnings would not have changed his decision to prescribe the TVT-O device. Even after he was presented with Ms. Sharp's criticism of the product warnings, he still testified that he would have taken the same course of action then as he would now, as his good opinion of the device had not changed. Accordingly, the Court finds that, pursuant to the learned intermediary rule, Dr. Crownover's independent knowledge has broken the causal link between allegedly deficient warnings and Ms. Sharp's injuries. Moreover, she has failed to meet proof with proof and offer the Court competing facts that would raise a genuine issue for trial.

IV. CONCLUSION

IT IS THEREFORE ORDERED that Defendants' Motion for Partial Summary Judgment (Doc. 20) is **GRANTED**, and Counts II–IV, VII, X–XIII, and XV are **DISMISSED WITH PREJUDICE**.

IT IS FURTHER ORDERED that Counts VI, VIII, IX, and XIV are voluntarily **DISMISSED WITHOUT PREJUDICE** by the Plaintiff pursuant to Federal Rule of Civil Procedure 41(b).

Counts I, V, and XVI–XVIII will remain for trial.

IT IS SO ORDERED on this 24th day of March, 2020.

TIMOTHY L. BROOKS
UNITED STATES DISTRICT JUDGE